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MIPR NO: 95MM5542

TITLE: Effects of Menstrual Phase on Pulmonary Function and Exercise Performance in Young Active Duty Women

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CONTRACTING ORGANIZATION: Walter Reed Army Medical Center Washington, DC 20307-5001

REPORT DATE: April 1996

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command Fort Detrick, Frederick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release; distribution unlimited

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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden. to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

		RT DATE 11 1996	3. REPORT TYPE A Final (21	Nov 94	- 31 Dec 95)
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Effects of Menstrual		•		0.5	
Exercise Performance in Young Active Duty Women			95M	M5542	
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Washington, DC 20307-5001					
9. SPORSORING/MONITORING	AGENCY NAME(S)	AND ADDRESS(ES	5)		NSORING / MONITORING
U.S. Army Medical Research and Materiel Command			AGE	NCY REPORT NUMBER	
Fort Detrick, MD		i materier Co	ommand	ı	
Fort Betrick, MB	21/02-3012				
44 CHERLESCENTERY NATE					
11. SUPPLEMENTARY NOTES					
12a. DISTRIBUTION / AVAILABILIT					
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FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the US Army.

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In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

Yes For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

NA In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

NA In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NTH Guidelines for Research Involving Recombinant DNA Molecules.

In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

Oleh W. Maj, MC 29 April 96

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Date

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INTRODUCTION:

Results of the 1988 Active Army Physical Fitness Survey¹ revealed that a significantly higher percentage of female soldiers between the ages of 17 and 26 failed the 2-mile-run portion of the Army Physical Fitness Test (APFT), compared to male soldiers of the same age. Successful completion of the APFT is critical to retention and promotion and presumably to combat readiness as well. In their study, O'Connor and Bahrke¹ note that "a large and unacceptable percentage of soldiers under the age of 35 may not possess the cardiovascular or muscle strength and endurance necessary to withstand exposure to prolonged combat." However, if the APFT is given to female soldiers during a phase of their menstrual cycle when their ability to perform maximally is reduced, this critical test would not be an accurate reflection of true maximal performance level.

There have been few studies about the effects of menstrual phase on pulmonary function and exercise performance published over the past 28 years. The studies that have been published were performed using a limited number of subjects and revealed conflicting results. In 1981, Schoene and colleagues reported a significant decrease in exercise performance during the luteal phase of the menstrual cycle in their six controls (women with normal menstrual cycles). These authors also demonstrated increased ventilatory drive and exercise ventilation during the luteal phase. In 1989, Nicklas and colleagues reported their observations of exercise response and muscle substrate responses in 6 eumenorrheic females. They exercised their subjects at 70% of predicted VO2max until exhaustion and found that exercise duration and glycogen repletion were greater at the mid-luteal phase, compared to the mid-follicular phase. These authors concluded that "...athletic performance may be affected by the phases of the menstrual cycle."

Chen and Tang⁴ investigated the effect of menstrual cycle on respiratory muscle function in 30 healthy adult women. Inspiratory muscle endurance (product of pressure load and sustained time; pressure-time index) was found to be greater in the mid-luteal phase, compared to the follicular phase. They concluded that "inspiratory muscle endurance is affected by the menstrual cycle". Interestingly, in that same study, no difference in resting pulmonary function was noted. De Souza and colleagues⁵ studied exercise performance in 8 eumenorrheic and 8 amenorrheic female runners. They found that oxygen uptake, minute ventilation, ratings of perceived exertion and time to fatigue were not affected by the phase of the menstrual cycle. Because of the small number of subjects involved in these studies, we believe there is inconclusive evidence to determine whether menstrual cycle phase affects pulmonary function and exercise performance. This study was designed to definitively determine if different phases of the menstrual cycle are associated with significant differences in pulmonary function, exercise performance and non-specific airway hyperreactivity.

BODY:

Methods:

All female soldiers between the ages of 17 and 26 taking the APFT during 1994 and 1995 at Walter Reed Army Medical Center, Ft. Belvoir and Ft. Meade were eligible for participation. We attempted to study two groups of female soldiers: female soldiers who passed the entire APFT (including the 2-mile-run) and female soldiers who did not pass the 2-mile-run portion of the APFT. Eligible subjects were identified by Master Fitness Trainers (MFT) at each U.S. Army post. These subjects were screened via telephone to identify only those individuals who were eumenorrheic and did not have a history of pulmonary disease.

Testing was performed at two times during the menstrual cycle: the early follicular phase (day 3 of the menstrual cycle) and the mid-luteal phase (day 23 of the menstrual cycle). Cycle phase was documented by serum estradiol and progesterone assays. The order of testing was randomized with respect to menstrual phase (follicular phase first versus luteal phase first) to help control for learning effect in performance of the various pulmonary and exercise tests. During each visit, after completion of a questionnaire, the following resting pulmonary function studies were performed: forced vital capacity (FVC), forced expiratory volume in one second (FEV1), single breath diffusing capacity for carbon monoxide corrected for hemoglobin (DLCO[Hgb corr]) , peak inspiratory pressure (PIP), peak expiratory pressure (PEP), and the respiratory muscle strength (RMS=[PIP + PEP]/2). These were immediately followed by exercise testing.

Exercise testing was performed on a cycle ergometer beginning with unloaded pedaling and progressing with increasing workload of 25 watts each minute to tolerance. A physician and a technician monitored the exercise testing. Continuous monitoring of ECG waveform and oxyhemoglobin saturation was performed. Maximal oxygen consumption (VO2max), oxygen consumption at anaerobic threshold (VO2@AT) and time of exercise (Exercise Time) were recorded. After exercise testing, spirometry was retested within 5 minutes.

If spirometry or clinical evaluation revealed no evidence of bronchospasm (a fall in FEV1 of \geq 10% at 5 minutes post exercise or wheezing), subjects recovered for 2 hours and then underwent bronchoprovocation testing. Forced spirometry was again repeated to obtain a baseline. This was followed by methacholine bronchprovocation. The Rosenthal dosimeter method was used, with gradually increasing doses of methacholine. The best pre-methacholine challenge FEV1 and FVC were compared to the lowest FEV1 and FVC after bronchoprovocation (DFEV1 and DFVC). A \geq 20% fall in FEV1 was considered positive for airway hyperreactivity.

Results:

Over five hundred servicewomen were identified as potential candidates for our study. Participating local Army facilities included Walter Reed Army Medical Center, Walter Reed Army Institute of Research, Fort Belvoir and Fort Meade. Telephone contact was attempted with *all* of these servicewomen. Approximately 50 agreed to participate and met inclusion criteria. PCS, ETS, pregnancy and not wishing to take part were common reasons for non-participation.

Of the approximately 50 servicewomen who initially agreed to participate, 31 servicewomen did not follow through on their initial agreement, for a variety of reasons. The data in this report reflects testing performed on the 19 servicewomen who completed the protocol by 31 December 95. All of these women passed their APFT.

The mean age of the nineteen servicewomen was 23.7 years \pm 1.9 years. (mean \pm S.D.). Nine were taking oral contraceptives. A summary of the mean values for test data is found in Table 1. Using the paired t-test we found no statistically significant differences in the studied variables, between days 3 and 23 of the menstrual cycle. The mean differences between each of the paired variables is displayed in Table 2. The use of contraceptives had no effect on maximal exercise oxygen consumption, exercise time or any test of pulmonary function.

TABLE 1. DAY 3 VS. DAY 23 VARIABLE VALUES

<u>Variable</u>	<u>N</u>	Mean	SD	Range
FEV1(3)[L]	19	3.07	0.39	2.45 - 4.02
FEV1(23)	19	3.09	0.33	2.49 - 3.83
FVC(3)[Ĺ]	19	3.66	0.47	2.88 - 4.73
FVC(23)	19	3.66	0.39	2.88 - 4.61
PIP(3)[mm Hg]	19	100.68	25.37	50.00 - 150.00
PIP(23)	19	98.47	23.89	50.00 - 150.00
PEP(3)[mm Hg]	19	147.58	37.57	100.00 - 220.00
PEP(23)	19	152.74	44.20	100.00 - 240.00
RMS(3)	19	124.13	28.53	80.00 - 185.00
RMS(23)	19	125.61	31.61	75.00 - 185.00
DLCO(3)(Hgb corr)				
[ml/min/mmHg]	15	23.16	3.21	16.57 - 30.32
DLCO(Hgb corr)(23)	15	24.30	3.88	19.87 - 33.48
Vemax(3)[L/min]	19	74.62	20.65	39.10 - 117.80
Vemax(23)	19	71.68	16.56	38.40 - 103.90
Exercise Time(3)[min]	19	462.95	86.12	315.00 - 664.00
ExerciseTime(23)	19	456.16	78.41	325.00 - 636.00
VO2@AT[ml/min](3)	19	871.95	204.77	563.00 - 1405.00
VO2@AT(23)	19	876.21	256.01	550.00 - 1620.00
VO2max(3)[ml/min]	19	1780.21	494.09	1044.00 - 2958.00
VO2max(23)	19	1754.47	462.12	1047.00 - 2795.00
DFEV1(3)[L]	18	6.67	7.52	0.00 - 33.00
DFEV1(23)[L]	18	6.11	4.93	-2.00 - 18.00
DFVC(3)[L]	18	4.22	5.49	-1.00 - 22.00
DFVC(23)[L]	18	4.00	4.51	-3.00 - 14.00

TABLE 2. DIFFERENCES BETWEEN DAY 3 & DAY 23 VARIABLES*

<u>Variable</u>	<u>N</u>	Mean Change	<u>SD</u>	95% CI
FEV1[L]	19	-0.021	0.17	-0.10 to 0.06
FVC[L]	19	-0.005	0.17	-0.09 to 0.08
PIP[mmHg]	19	+2.21	10.83	-3.01 to 7.43
PEP[mmHg]	19	-5.16	26.37	-17.87 to 7.55
RMS	19	-1.47	17.46	-9.89 to 6.94
DLCO(Hgb corr)				
[ml/min/mmHg]	15	-0.32	2.37	-1.64 to 0.99
Vemax[L/min]	19	+2.94	11.87	-2.78 to 8.66
Exercise Time[min]	19	+6.79	22.68	-4.14 to 17.72
VO2@AT[ml/min]	19	-4.26	123.09	-63.59 to 55.06
VO2max[ml/min]	19	+25.74	141.12	-42.28 to 93.75
DFEV1[L]	18	+0.56	7.19	-3.02 to 4.13
DFVC[L]	18	+0.22	5.77	-2.65 to 3.09

^{*} All p values > 0.05

Discussion:

To date, this is the largest reported study evaluating the effect of menstrual phase on pulmonary function, exercise capacity and non-specific airway hyperreactivity. Our results are similar to those of De Souza⁵ and support the premise that the phase of the menstrual cycle has no influence on pulmonary function and exercise capacity. They are also similar to those reported by Pauli and colleagues⁶, who found no difference in airway hyperreactivity in a group of 29 healthy women whose mean age was 30.3 years. Therefore, the differences in failure rates on the 2-mile-run between 17 to 26 year old women and men, reported in the 1988 Active Army Physical Fitness Survey¹, cannot be explained by changes in pulmonary function, exercise capacity or airway hyperreactivity during the servicewomen's menstrual cycle.

Therefore, the APFT can be administered at any time during a servicewoman's menstrual cycle. Failures on the 2-mile-run should not be attributed to phase of the menstrual cycle.

There are several limitations to our study. First, the numbers are not as large as anticipated. Despite screening over a half-thousand women, only 1% agreed to be studied. Although PCS, ETS and pregnancy were common causes of not participating, not wishing to take part was the most common reason. Given the potential impact of finding a difference between days 3 and 23, it is hard to understand why servicewomen did not want to participate. Second, no servicewoman who did not pass the APFT 2-mile-run volunteered to be studied. Unfortunately, it was this group of women in whom we had the most interest. Although it is unlikely that this group is any different than the women in our study or that of De Souza, the small possibility still exists.

CONCLUSIONS:

The phase of the menstrual cycle has no impact on pulmonary function, maximal exercise performance or airway hyperreactivity in this group of servicewomen. The APFT can be administered to servicewomen at any time, without taking into account the phase of the menstrual cycle.

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APPENDIX:

No publications or meeting abstracts are in print at the time of this report. Mr. Angel Sierra is the only person who received pay from this protocol.